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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,016	10/02/2000	Keith P. Wilson	VPI/96-03 DIV2	7947
1473	7590	10/19/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/678,016

Applicant(s)

WILSON ET AL.

Examiner

Marianne P. Allen

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 27-34, 37, 38, 40, 41, 44, 47, 63 and 72-85 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23, 27-34, 37, 38, 40, 41, 44, 47, 72-84 is/are allowed.
- 6) ☒ Claim(s) 63, 85 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1647

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/5/05 has been entered.

Claims 1-22, 24-26, 35-36, 39, 42-43, 45-46, 48-62, and 64-71 have been cancelled. Claims 72-85 have been newly introduced. Claims 41, 44, and 47 were previously withdrawn but will now be rejoined.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 85 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method steps of claim 85 are limited to manipulation of data. Such methods are non-statutory. There are no pre- or post-computer activities. The method steps as written do not result in a concrete, tangible, and useful result. Note that docking alone (with or without molecular dynamics or energy minimization) does not result in an inhibitor. See MPEP 2106.

Claim Rejections - 35 USC § 112

Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 85 has been newly introduced. No basis is seen in any of the sections pointed to by applicant for a method of designing an IMPDH inhibitor where the steps are limited to docking a chemical entity possibly followed by molecular dynamics or energy minimization.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 refers to step d) with respect to selecting the chemical entity. This is confusing as step d) in claims 23, 29, and 32 concerns output. It appears that step e) may have been intended.

Claim 85 is confusing in being directed to a method for designing an IMPDH inhibitor. The method as written has no steps for designing an inhibitor and does not result in providing an inhibitor. The only steps are docking a chemical entity possibly followed by molecular dynamics or energy minimization.

Art Unit: 1647

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kunz et al. (1982).

Kuntz et al. teaches the computer program DOCK. This program was used for design of inhibitors by shape complementarity by docking ligands and receptors. Note further that the specification indicates on pages 29-32 that such modeling programs would have been well known.

Claim 85 is directed to a method for designing an inhibitor comprising docking a chemical entity with all or any part of a binding pocket defined by given structure coordinates. The docking can use shape complementarity. The recited structural coordinates are considered to be nonfunctional descriptive material as it functions as input to the computer means. As the recited steps of the method are met by Bohm, each of the claims is obvious over this known method. How the program of Bohm functions is not altered by the input.

Applicant is reminded that MPEP 2106 states:

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot

Art Unit: 1647

render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the encoded on the medium, invention.

Conclusion


Claims 23, 27-34, 37-38, 40-41, 44, 47, 72-83 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1647
10/12/05

Application/Control Number: 09/678,016

Page 6

Art Unit: 1647

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